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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,215	07/30/2001	Jean Francois Michelet	P66893US0	8358

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10/01/2002

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/01/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,215

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 4 is objected to because of the following informalities: the recitation "water or water" appears to be a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 13-16, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification and prior art do not enable (1) method of stopping the loss of hair; and (2) method of using prostaglandins EP-2 and EP-4 receptor agonists. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the

invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

(1) Applicants' disclosure fails to enable the claimed method of "stopping the loss of hair". The burden of enabling the prevention of a natural condition such as the loss of hair (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen the subjects for prolonged period of time. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about stopping the loss of hair within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in stopping the hair loss. Undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method.

(2) There is no guidance as to how a skilled artisan would define or obtain the EP-2 and EP-4 type receptor agonists. There is no working examples to demonstrate attenuating or reducing the hair growth by using the claimed method using these compounds. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in attenuating or reducing hair growth rate. The specification fails to enable the compositions comprising the EP-2 and EP-4 receptor agonists, and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method.

Following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 14, and 19 provide for the use of prostaglandin EP3 receptor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 13-16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Katsu et al. (CAPLUS abstract data 1987:55617, JP 61218510).

The Katsu abstract discloses a hair tonic composition comprising 200 µg of prostaglandin E1 in 40 mL of water (0.005 % by weight). See instant claims 1, 2, 13-16, and 19. The reference teaches that PGE 1 and PGI 2 promote human hair growth. Examiner takes the position that claimed method of “attenuating, reducing, and stopping the loss of keratin materials” is within the scope of the prior art which uses the same

active compound in promoting hair growth, which would result in overall reduction of loss of hair.

2. Claims 1, 13-16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanson (US 5605931).

Hanson discloses method of reducing hair loss by administering PGE 1. See Example 1; col. 6, line 6 – col. 7, line 7. The reference specifically teaches that for protection of hair follicles topical administration is especially suitable. See col. 7, lines 6-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 2-12, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson as applied to claims 1, 13-16, and 19 above, and further in view of Bradbury et al. (US 6124362) ("Bradbury") and Bernard et al. (US5985841) ("Bernard").

Hanson, discussed above, further teaches that about 5 –800 μ g of the prostaglandins per unit dosage form can be used. See col. 7, lines 26 – 42; instant claims 2 and 18. Optimization of the weight amount of the prostaglandin for desired effectiveness or strength of the active ingredient would be obvious to a routineer. The reference further teaches 16,16-dimethyl PGE₂, which is viewed as an EP-2 type prostaglandin receptor agonist. See col. 6, lines 5 – 38. See also Konger et al. (Biochimica et Biophysica Acta 1401, 1998) 221-234, Table 1. The reference fails to teach the types or the constituents of topical compositions containing the prostaglandins.

Bradbury teaches hair loss treatment compositions for topical use. See abstract. The reference discloses cosmetically acceptable vehicles and ingredients, such as polyols, fatty components, and surfactants. See col. 12, line 20 – col. 25, line 39. See instant claims 4, 5, 7, 9, 10, 11. Examples also illustrate formulation comprising organic solvents. See Examples 1-5; instant claims 7 and 8. Furthermore, optionally using prostaglandin agonists or antagonists is mentioned. See col. 24, lines 23 – 29.

Hanson and Bradbury fail to disclose the pH of the composition.

Bernard teaches composition for hair and scalp useful for hair growth regulation. See abstract. The reference teaches that the pH of the compositions ranges from 3 to 9. See col. 4, lines 4 – 13. See instant claim 12.

Given the specific teaching in Hanson that topical application of E-type prostaglandins are effective in reducing hair loss, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked for prior arts such as Bradbury for conventional topical formulations for hair loss in expectation of successfully formulate a topical composition for alopecia. The skilled artisan would have also adjusted the pH of the composition suitable for hair/scalp use, as taught by Bernard.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-36 of copending Application No. 09/917211 or claims 1-20 of copending Application No.

09/917274. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is directed to method of reducing hair growth by using composition comprising prostaglandin EP3 receptor agonist with EP2 and/or EP4 receptor agonists.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
September 30, 2002


SREENI PADMANABHAN
PRIMARY EXAMINER 10/1/02